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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/359,260	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76,82-95,131,132 and 134-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76,82-95,131,132 and 134-138* is/are rejected.

7)☒ Claim(s) *91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Claim Objections

Claim 91 is objected to because of the following informalities:

Claim 91 recites the limitation of "measuring the indicia said activity" and should be amended to read as --measuring the indicia of said activity--. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The rejection of claims 76, 82-95, 131, 132, and 134-138 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete is withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 76, 82, 87-95, 131, 132, and 134-138 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostrem et al. This rejection is maintained and reiterated from the previous Office action.

The instant claims are drawn to methods of identifying a peptide with a desired activity having an indicia that satisfies a test requirement comprising the steps of identifying a predetermined set of peptides, parameterizing the predetermined set of peptides by determining for each peptide a first whole molecule parameter and a second parameter that is dependent on the specific order of constitutive subunits within each peptide, performing a space filling design model of the parameterized peptides to identify a first peptide library, constructing a first test peptide library comprising a plurality of the first test peptides identified using a space-filling model, determining an activity of said plurality of first test peptides, measuring the indicia of said activity, deriving a quantitative relationship between said indicia of said activity, and said first and second parameters, calculating an estimated indicia for each remaining peptide from said predetermined set of peptides using said quantitative relationship, setting a test requirement having a test indicia range, selecting a second test peptide library different from said first test peptide library, measuring the indicia of each second test peptide, and identifying at least one second test peptide having a measured indicia that satisfies said test requirement.

[Claims 94, 95, 132, 134, 135, 137, and 138]: Ostrem et al. sets forth a procedure for drug discovery by the preparation of a octamer combinatorial test peptide library in order to identify leads compounds therein, which reads on the claimed limitation of identifying a predetermined set of peptides (see Ostrem et al., at least Abstract and page 1054, column 1, first paragraph). The library set forth in Ostrem et al. comprises peptides of 8 amino acids in length and have been evaluated as having a

potency of 4 to 15 μM and retain an unusual selectively for factor Xa over thrombin, which reads on the instantly claimed determination of a first whole molecule parameter and a second parameter that is dependent on the specific order of constitutive subunits. Ostrem et al. discloses the construction of a combinatorial library of peptides as containing a multitude of varying peptide sequences in order to investigate changes in peptide properties that can be correlated to specific sequence changes, and as such provides a space-filling model wherein variations of octamer peptides have been explored in both a sequence and conformational space context (see Ostrem et al., at least Abstract and page 1053, column 1, line 1 through column 2, line 32), which reads on the claimed limitation of constructing a first test peptide library comprising a plurality of first test peptides identified using a space-filling design.

Further, the teaching of Ostrem et al. that the peptides in the library have a measurable of binding factor Xa, which reads on the claimed measuring the indicia of an activity of a plurality of first test peptides (see Ostrem et al. Abstract and page 1053, column 2, lines 23-32). The described procedures for testing a family of combinatorial peptides of 8 amino acids in length to bind factor Xa and level of potency reads on the claimed determination of a relationship between an indicia of activity, a first parameter, and a second parameter (see Ostrem et al., page 1054, column 1, line 1 through page 1055 column 1, line 41). Ostrem et al. further sets forth four separate assays that are described and performed on peptides identified from an initial set of combinatorial octamer peptides, wherein peptide-bound beads are separately prepared and used in each of the four distinct assay (see Ostrem et al., page 1054, column 2, line 1 through

page 1055, column 1, line 41). The selection of peptides based on the results of these assays reads on the instantly claimed limitations of setting a test requirement having a test indicia range, selecting a second test peptide library different from said first test peptide library, measuring the indicia of each second test peptide, and identifying at least one second test peptide having a measured indicia that satisfies said test requirement.

[Claim 76]: Evaluating the potency of the octamer combinatorial peptides set forth by Ostrem et al. sets forth a determination the potency is a function of peptide sequence composition, which reads on the claimed limitation of determining a relationship comprising the step of determining $y_i=f(x_{ij})$, wherein potency is the whole molecule parameter X_{ij}, i represents the number representative of octamer peptide tested, j ranges from 1 to d, and d is 1 as only one whole molecule parameters is evaluated, and y_i represents potency, the activity being determined for each octamer combinatorial peptide.

[Claim 82]: Identifying a subset of the first peptide library and, based upon their ability to bind factor Xa, using the peptides in a prothrombinase assay set forth by Ostrem et al. reads on the instantly claimed space-filling design expanding less than all of the first test peptides into their constituents.

[Claims 87-90 and 93]: The ability of test peptides to bind to factor Xa reads on the claimed activity of binding to a receptor and the claimed activity is inducement of activation of a receptor within a cell.

[Claim 91]: Ostrem et al. sets forth in the Factor Xa assay the addition of peptide stock solutions to substrate media in half-area microtiter plates, which reads on the instantly claimed limitation of forming a plurality of culture media each containing a respective test peptide. See Ostrem et al., page 1054, column 2, lines 19-42.

[Claim 92]: Part of the disclosed library screening process includes the step of incubating destained beads with the factor Xa-SAP-inhibitor mixture. See Ostrem et al., page 1054, column 1, first paragraph. The disclosed determination of activity is interpreted as peptides being exposed to an incubation process with the inhibitor mixture set forth by Ostrem et al. reads on the instantly claimed inhibition of activation of a receptor. Further, the step of incubation reads on a step of adjusting said test requirement by a desired value for improving results of said step of selecting a new second peptide library.

[Claim 131]: Page 39, lines 7-34 of instant specification provides an exemplary embodiment of using a space-filling design wherein a particular cut-off distance for potential lead-compounds that is used to identify compounds of interest. In this example, the "distance function" that was applied was an arbitrary cut-off limit for the variability of the specific characteristics of peptide hydrophobicity and total dipole moment. Figure 4, Table 2, and pages 1056, line 1 through page 1057, column 2, line 2 of Ostrem et al. sets forth that identification of lead compounds comes from the assessing the plotted estimated values of relative activity, protein concentration, and inhibition. Further, Figure 5 and page 1057, column 2, line 4 through page 1058, column 2, line 5 of Ostrem et al. further discusses the criteria that were used to distinguish and

identify novel lead compounds from amongst all compounds utilized in the investigation., which is interpreted as the application of a distance function which is consonant with the above described example provided in the instant specification. Therefore, the above described method of identifying novel ligands by Ostrem et al. reads on the claimed limitation of a space-filling design that applies a distance function.

[Claim 136]: Page 45, lines 6 and 7 of the instant specification defines the claimed term "compound isomers" as "the group of compounds sharing common global characteristics". The procedures disclosed by Ostrem et al. utilize biotin labeled protein to attach peptides from libraries to beads, and thus produce a library of bead-bound peptides. The beads are then utilized in specific assayed for activity against purified proteins and result in the identification of peptides with a desired property, thus allowing for the specific selection of beads containing peptides of a desired property. Since the peptides attached to a bead are not constrained in any manner, the structural variability for a group of peptides is unrestrained, the peptides necessarily sample any and all alternative conformations that are specific to a given octamer sequence. As such, the disclosed procedures reads on the instantly claimed steps of expanding first test peptides into their compound isomers and performing a space-filling design on said constituent compound isomers to identify candidate peptides.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 76, 82-95, 131, 132, and 134-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrem et al. in view of Cramer (US Patent No 6,240,374).

The instant claims are drawn to methods of identifying a peptide with a desired activity having an indicia that satisfies a test requirement as discussed above and further limiting the group that a first parameter and second parameter may be selected from.

[Claims 83-86]: As discussed above, Ostrem et al. sets forth a procedure for drug discovery by the preparation of a octamer combinatorial test peptide library in order to identify leads compounds therein. However Ostrem et al. does not fairly teach the parameterization a predetermined set of peptides using a first and second parameter selected from the groups recited in instant claims 83-86.

Cramer et al. sets forth a method of validating molecular structural descriptors that may be used to select optimally diverse subsets of molecules with a desired set of characteristics. See Cramer et al., Abstract. Cramer et al. further discloses an example wherein a library database of compounds is selected for on the basis of molecular weight and hydrophobicity (see column 62, lines 38-50).

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to parameterize peptides on the basis of molecular weight and hydrophobicity, as taught by Cramer used in the procedure for drug discovery as set forth by Ostrem et al. because Cramer et al. teaches that the optimizing the characteristics of compound libraries utilized in drug discover is critical for establishing a sufficiently diverse but manageable set of starting compounds for further investigation (see Cramer, column 2, lines 51 through column 3, line 67).

Response to Arguments

Applicant's arguments filed 31 January 2006 have been fully considered but they are not persuasive.

In regards to the rejection of claims as being anticipated by Ostrem et al., applicants argue that Ostrem et al. fails to provide a disclosure sufficient for enabling one of skill in the art to identify peptides having a desired activity.

In response, it is noted that Ostrem et al. fully discloses all experimental procedures relied upon in the experimental assays as well as several additional references further describing the experimental protocols (see Ostrem et al., page 1054, column 1, line 1 through page 1055, column 1, line 41), several examples of successfully identifying peptides using the disclosed methodology are provided (Tables 1 and 2, Figures 1 and 2, and page 1055, column 1, line 43 through page 1057, column

2, line 2), and further the reference of Ostrem et al. has been published in a peer reviewed journal. Further, MPEP § 2121 states that when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980) (see also MPEP § 716.07). Apart from arguments alone, applicants have not submitted any factual evidence that draws into question the validity of the results published by Ostrem et al.

Applicants further argue that Ostrem et al. does not disclose or teach the essential step of performing a space-filling design or the generation of a first peptide library, and further that the disclosure of a split-synthesis by Ostrem et al. method clearly does not show that a space-filling design was applied.

In response, it is noted that an explicit definition of a space-filling design is not provided in the instant disclosure nor do the claims specify a definition for a space-filling design. In the instant rejection, Ostrem et al. is relied upon as disclosing the construction of a combinatorial library of peptides as containing a multitude of varying peptide sequences in order to investigate changes in peptide properties that can be correlated to specific sequence changes, and as such provides a space-filling model wherein variations of octamer peptides have been explored in both a sequence and conformational space context. Applicants arguments do not point to any limitation of the instant claims or a definition of a space-filling design that would exclude the

embodiment as taught by Ostrem et al. As such, applicants arguments are not found persuasive.

Applicants further argue that Ostrem et al. fails to disclose the claimed feature of parameterizing the predetermined peptides through determination of first and second parameter, and that the determination of a peptide of length 8 amino acids simply cannot be interpreted as reading on the claimed step of determining a second parameter which depends on the specific order of constitutive subunits within each desired peptide.

In response it is noted that the independent claims 135-138 generically recite determining a first parameter that is a whole molecule parameters and a second parameter that is dependent of the specific order of constitutive subunits of the predetermined peptides. As such, any parameters that are whole molecule parameters or are dependent on the specific order of constitutive subunits anticipates would meet the instantly claimed limitations of a first or second parameter, respectively. In the instant case, the assessment and measurement of a given peptides ability to bind factor Xa reads on the claimed limitation of a whole molecule parameter as the ability of a given to bind factor Xa is dependent upon particular sequence and specific conformation of said peptide to recognize and bind to factor Xa with a quantifiable level of selectivity. This property is dependent on the entirety of the peptide as a whole and thus reads on a whole molecule parameter. Further the peptide library disclosed by Ostrem et al. relies upon varying peptide sequences to sample how sequence variations

will effect peptide binding to factor Xa. As such, each distinct peptide in the disclosed library is directly dependent upon the order of amino acids of the peptide sequence. The sampling of sequence variations of peptides forms part of the basis for selecting the peptides contained with the library and thus reads on the claimed limitation of a second parameter that is dependent on the specific order of constitutive subunits. Applicants arguments also fail to point to any definition in the instant specification or claimed limitation would explicitly exclude the embodiments of a first and second parameter relied upon in the instant rejection.

Applicants further argue that Ostrem et al. does not disclose or suggest deriving a quantitative relationship between the measured indicia between the measured indicia, the first parameter, and the second parameter nor does Ostrem et al. disclose the step of calculating an estimated indicia using the derived relationship.

In response, it is noted that the construction of a peptide library in Ostrem et al. containing a multitude of varying peptide sequence constructs is based on the asserted relationship that the affinity of a given peptide is directly related to the sequence of said peptide (see page 1053, column 2, lines 23-32), that a given peptide may be selected for a high affinity of binding factor Xa, and the affinity of selected peptides may be further quantified through a measurement of the peptides binding affinity. In the instant case, Ostrem et al. has set forth a measurable (and thus quantifiable) relationship derived between the binding affinity of a given peptide for factor Xa (said indicia of said activity and said first parameter) and the sequence of the given peptide (said second

parameter). It is also noted that the instant claims do not exclude embodiments wherein there is overlap between the measurable indicia of activity and first and second parameters. Ostrem et al. further provides examples of peptides with a high binding affinity for factor Xa as well as the calculation characterization of their specific binding affinity (see for example Tables 1 and 2 and Figures 1 and 2 of Ostrem et al.)

Applicants further argue that Ostrem et al. never goes outside the original combinatorial library to identify peptides that have not yet been assayed.

In response, it is noted that the instant claims recite the limitation of "selecting a second test peptide library comprising at least one second test peptide... wherein said second test peptides are not in said first library" (see for example lines 23-26 of instant claim 135). In regards to this limitation, Ostrem et al. is relied upon for disclosing the use of four separate and distinct assays each performed on distinct peptides sets identified from an initial set of combinatorial octamer peptides (see Ostrem et al., page 1054, column 2, line 1 through page 1055, column 1, line 41). As such, Ostrem et al. sets forth the multiple test peptide libraries wherein any two selected sets of assayed peptides read on the instantly claimed limitation of a first peptide library and a second test peptide library comprising peptides that are not in said first library.

Applicants further argue that Ostrem et al. fails to teach or suggest the application of a derived quantitative relationship to calculate an estimated indicia for

peptides. In addition applicants argue that the curves plotted in Figures 1 and 2 do not demonstrate the calculation of an of estimated indicia of activity.

In response, it is noted that measured values of several peptides competitive inhibition of factor Xa have been calculated and displayed in Figures 1 and 2. These figures further provide plotted curves for competitive inhibition on over regions wherein explicit measurements where not taken. As such, a calculated estimate of a given peptides activity is provided by the plotted curves in regions of where measured data points are not provided. As such, the plotted data and extrapolated curves in said figures provides a demonstration of both measurements and estimations of competitive inhibition of peptides against factor Xa, which reads on the claimed limitations drawn to determining and measuring indicia of activity as well as calculating an estimated indicia for candidate peptides.

Applicants further argue that Ostrem et al. does not disclose a single formula in regards to determining a quantitative relationship or calculating an estimated indicia of activity, that once a quantitative relationship is determined an estimated indicia is calculated for peptides that have not been previously screened, that a test requirement must necessarily be set prior to testing peptides, an evaluation of a quantitative relationship on tested versus untested peptides, or that peptides derived from the process are capable of performing their intended application without further modification.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of a formula in determining or measuring an indicia of activity, an estimated indicia is calculated for peptides that have not been previously screen, that a test requirement must necessarily be set prior to testing peptides, an evaluation of a quantitative relationship on tested versus untested peptides, or that peptides are capable of performing their intended application without further modification) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In regards to the rejection of claims as being unpatentable over Ostrem et al in view of Cramer, applicants argue that Cramer does not appear to disclose the features recited in claims 83-86.

In response, it is noted that applicants acknowledge Cramer as disclosing the construction database of molecules comprising the property of hydrophobicity. It is further noted that instant claims 83-86 are drawn to selecting first and second parameters from several listed features, which includes both molecular weight (as a possible first parameter) and hydrophobicity (as a second parameter). Cramer et al. sets forth an example of the combined use of molecular weight and hydrophobicity metrics in the construction and selection of molecules in a library (see especially column

column 62, line 38-50), which reads on one embodiment of the first and second parameters as instantly claimed.

Applicants further argue that neither reference provides for any motivation to seek out the teachings of the other with a realistic expectation of arriving at the claimed invention. Applicants further argue that even if Ostrem et al. and Cramer were properly combinable, the combined teachings would be insufficient to render the claimed invention obvious.

In response, it is noted that the instant rejection provides as motivation to combine the two references the teaching from Cramer that the optimizing the characteristics of compound libraries utilized in drug discover is critical for establishing a sufficiently diverse but manageable set of starting compounds for further investigation (see Cramer, column 2, lines 51 through column 3, line 67). Further, the peptide libraries disclosed by Ostrem et al. comprises peptides that may be selected by application of criteria drawn to molecular weight and hydrophobicity as taught by Cramer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER